

**REMARKS**

Applicants gratefully acknowledge the Examiner's statement in the Office Action mailed August 9, 2006 that claims 11-14 are allowed. The Examiner rejected the remaining claims as being patentable over various references. Specifically, the Examiner rejected claims 1, 3, 4, 9, 10, 29 and 30 under 35 USC 102(b) as being anticipated by U.S. Publication No. US 2002/0069870 A1 to Farmer, claims 24-27 and 31 under 35 USC 103 as being obvious over Farmer, claims 5-7 as being obvious over Farmer in view of U.S. Patent No. 6,527,011 to Mantz and claims 8 and 28 as being obvious over Farmer in view of U.S. Patent No. 6,279,574 to Richardson. Applicants respectfully disagree for the reasons set forth below.

**Remarks About a Second Supplemental Information Disclosure Statement:**

Applicants timely mailed a Second Supplemental Information Disclosure Statement (Second Supp. IDS) on October 10, 2006, and made therein an appropriate statement under 37 CFR 1.704(d), which is more restrictive than the statement under 37 CFR 1.97(e)(1). Nonetheless, for the sake of completeness, Applicants, through their undersigned attorney, do hereby state that each item of information contained in the Second Supp. IDS mailed October 10, 2006 was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Second Supp. IDS.

Accordingly, Applicants respectfully request that the Examiner consider the references submitted with the Second Supp. IDS and initial the Form PTO-1449 enclosed therewith. Should the Examiner have any questions about the Second Supp. IDS, Applicants respectfully invite him to contact the undersigned attorney at his convenience.

**Remarks About The Prior Art Rejections:****Claims 1 and 5-11:**

Applicants have amended claim 1 to recite “a first inhalation conduit communicating with said output end of said chamber, said first inhalation conduit comprising *an inlet communicating with said output end of said chamber housing and an outlet* adapted to transmit medication to the patient, *wherein said inlet and outlet are axially aligned with said output end of said holding chamber,*” and “an exhaust conduit communicating with said first inhalation conduit at a location positioned *between said inlet and said outlet of said first inhalation conduit.*” In this way, as shown for example and without limitation in the embodiment of FIG. 1, medicament traveling with the oxygen passes “through the output end 10 of the holding chamber 4 and through the inhalation circuit 88, formed at least in part by the passageway 68 and the patient interface element 86, 98” (Specification at 8, lines 24-26). As such, the medicament can easily flow along an axially extending path.

In contrast, the inlet and outlet of the inhalation conduit of Farmer, as applied by the Examiner (Office Action at 3), are not axially aligned. Rather, in all embodiments, Farmer discloses a T-shaped delivery tube 17 having an outlet extending substantially perpendicular to the inlet (Farmer at FIGS. 1-8). Applicants note in this respect that the Examiner applied the portion of the delivery tube “located just before the exhaust valve 21” as the recited *exhaust* conduit, rather than as a portion of the inhalation conduit.

For all of these reasons, Farmer does not disclose or suggest the recitations of claim 1, or claims 5-10 depending therefrom, and Applicants respectfully submit that those claims be passed to allowance on the next Office Action.

**Claims 3 and 4:**

Amended claim 3 recites a “second inhalation conduit comprising an oxygen intake line communicating with said one-way inhalation valve” and “a pressurized metered dose inhaler in flow communication with said *second inhalation conduit downstream* of said one-way inhalation valve.” Neither of the embodiments (FIGS.

1-4 or FIGS. 5-8) of Farmer disclose or suggest an inhaler in flow communication with the second inhalation conduit, which communicates with the “input end of the holding chamber.” Rather, in the first embodiment, as shown in FIG. 3, the medicants from the canister 11 of Farmer pass *directly* through “channel 13 into collapsible reservoir 14” (Farmer at para. 24). The end of the channel 13 is disposed *in the reservoir*, not in communication with the second inhalation conduit.

Likewise, in the embodiment of FIGS. 5-8, the MDI canister 32 of Farmer delivers medicament directly into the reservoir 14, and is not in “flow communication with said *second inhalation conduit downstream* of said one-way inhalation valve” as recited in claim 3.

Finally, and contrary to the Examiner's assertions, Farmer does not disclose or suggest that the conduit, housing the one-way valve 16 in the embodiment shown in FIG. 1, includes an “oxygen intake line” (Office Action at 2-4, paras. 4 and 5). Rather, Farmer simply discloses that “air” enters the reservoir 14 through the valve 16 (Farmer at Col. 2, paras. 22 and 25). Instead, Farmer discloses only that in a second embodiment of FIGS. 5-8, a T-fitting 40 may be provided for use with “an auxiliary oxygen supply hook-up” (Farmer at para. 27). As just noted, however, in either embodiment, the MDI canister is not in communication with the inhalation conduit.

Accordingly, because Farmer does not teach every element of claim 3, the Examiner's rejections should be withdrawn.

#### **Claims 24-27:**

Applicants have rewritten claim 31 in independent form (see amended claim 24). Claim 24 now recites “transmitting oxygen from *a ventilator* through a holding chamber and an inhalation conduit to the patient during an inhalation sequence of a breathing cycle . . . and transmitting said substantial portion of said exhaust gas from said exhaust conduit *to said ventilator* during said exhalation sequence.” In the outstanding Office Action, the Examiner asserts that it would have been obvious to modify Farmer to couple the assembly to a ventilator, relying on a generalized statement in the Background section that refers to a collapsible reservoir being used in

a ventilator breathing circuit (Office Action at 5-6, citing Farmer at para. 4). Nothing in that passage of Farmer, however, refers to the suitability of incorporating the disclosed reservoir of Farmer into such a ventilator circuit, and Farmer in fact teaches against such an application.

In particular, and as noted above, Farmer discloses in one embodiment (FIGS. 1-4) introducing "air" into the reservoir (Farmer at paras. 22 and 25) and, in a second embodiment (FIGS. 5-8), introducing oxygen into the reservoir. In both embodiments, however, the device exhausts gases through valve 21 to the *ambient environment*, not to a ventilator.

Moreover, Farmer discloses the use of an exhaust peep valve 21, which creates resistance during exhalation and prevents the patient from exhaling too quickly (Farmer at paras. 23 and 24). The configuration of the valve 21 which creates resistance during breathing, and which is capped, is not suited for use with a ventilator circuit, and there is no disclosure or suggestion in Farmer that an exhaust line can be secured to the delivery tube at the end containing the valve 21. Simply put, Farmer does not disclose all of the limitations of claim 24, and there is no suggestion to modify Farmer to incorporate the therapy device into a ventilator circuit.

**Claim 32:**

Claim 32 depends from claim 24 and is patentable over Farmer for all of the reasons set forth previously. Applicants note, however, that claim 26 further recites "wherein said introducing said medication into said holding chamber comprises introducing said medication into said inhalation conduit between said holding chamber and said one-way valve." As explained above with respect to claim 3, the only embodiment of Farmer that discloses a gas source is shown in FIGS. 5-8. In that embodiment, however, the medication is introduced directly into the reservoir 14 of Farmer, rather than into the conduit communicating with the reservoir. Accordingly, Applicants respectfully submit that claim 32 is patentable over Farmer for this additional reason.

**Claims 28-30:**

Applicants have rewritten each of claims 28 and 30 in independent form. Applicants respectfully submit that each of claims 28 and 30 are patentable over Farmer.

Claim 28 recites “a WYE connector connecting said second inhalation conduit and said exhaust conduit.” Without disputing whether or not Richardson discloses a WYE connector (Office Action at 7), Applicants respectfully submit that there is no suggestion to incorporate such a connector into Farmer. Indeed, Farmer does not disclose or suggest *any connection* between an exhaust conduit and a *second* inhalation conduit coupled to the *input end* of the reservoir as recited in claim 28.

Moreover, as set forth above with respect to claim 24, Farmer does not disclose or suggest connecting the “exhaust conduit” to any other structure, whether a ventilator or a WYE connector or both. Rather, the valve 21 of Farmer is expressly disclosed as venting to the ambient environment. Accordingly, Applicants respectfully request that claim 28 be passed to allowance on the next Office Action. For the same reasons, Applicants request that claim 30, which recites that “said oxygen intake line and said exhalation conduit are connected to a ventilator,” also be passed to allowance.

**Claim 33:**

New claim 33 recites that “a flow path between said interior of said chamber housing and said outlet of said first inhalation conduit through said output end of said chamber housing is free of any valve structure.” In contrast, Farmer discloses that “a one-way proximal diaphragm valve 19 as shown in FIGS. 1 and 2 prevents exhaled gases from entering reservoir 14” (Farmer at para. 24). As shown in FIGS. 1 and 2 of Farmer, the one-way valve 19 is positioned at the interface of the reservoir 14 and the delivery tube 17. Accordingly, Farmer does not disclose or suggest a flow path free of any valve structures, as set forth in claim 33, and Applicants respectfully request that the Examiner allow claim 33 on the next Office Action.

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**CONCLUSION:**

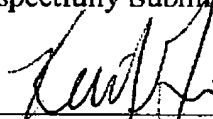
The Director is authorized to charge payment of the \$800 in additional claim fees (four (4) additional independent claims), or any other fees associated with this communication, to Deposit Account No. 23-1925.

If for any reason this application is not considered to be in condition for allowance and an interview would be helpful to resolve any remaining issues, the Examiner is respectfully requested to call the undersigned attorney at (312) 321-7732.

Respectfully Submitted,

Dated: November 10, 2006

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